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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,035	12/11/2000	Jas C. Lang	22727/04078	9153
7590	05/24/2006		EXAMINER	
Pamela A Docherty Calfee Halter & Griswold 1400 McDonald Investment Center 800 Superior Avenue Cleveland, OH 44114			AEDER, SEAN E	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 05/24/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action Before the Filing of an Appeal Brief</b>	Application No.	Applicant(s)
	09/674,035	LANG, JAS C.
	Examiner	Art Unit
	Sean E. Aeder, Ph.D.	1642

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 May 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1.  The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a)  The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2.  The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3.  The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a)  They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b)  They raise the issue of new matter (see NOTE below);  
 (c)  They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d)  They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4.  The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5.  Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.

6.  Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7.  For purposes of appeal, the proposed amendment(s): a)  will not be entered, or b)  will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1,23-25,27 and 28.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

AFFIDAVIT OR OTHER EVIDENCE

8.  The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9.  The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10.  The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11.  The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached pages.

12.  Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_

13.  Other: \_\_\_\_\_.

***Advisory Action***

The Amendments and Remarks filed 5/11/06 in response to the Final Rejection of 3/13/06 have been entered.

Claims 1, 23-25, 27, and 28 are pending.

Claims 1, 27, and 28 have been amended by Applicant.

Claims 1, 23-25, 27, and 28 are currently under consideration.

***Rejections Withdrawn***

The rejection of claims 1, 23-25, 27, and 28 under 35 U.S.C., first paragraph, as failing to comply with the written description requirement, is withdrawn in view of amendments.

The rejection of claims 1, 23-25, 27, and 28 under 35 U.S.C., second paragraph, as being vague and indefinite, is withdrawn in view of amendments.

***Response to Arguments***

Claims 1, 23-25, 27, and 28 remain rejected under 35 U.S.C., first paragraph, as failing to comply with the enablement requirement, for the reasons of record and the reasons set-forth below.

The claims are drawn to a method of detecting the presence of at least one squamous cell carcinoma and prostate cancer in a subject comprising assaying the

expression of a nucleic acid having "a sequence of" either SEQ ID NO:1 or SEQ ID NO:3 in *any* tissue sample that is suspected of being cancerous.

In response to the Final rejection of 3/13/06, Applicant amended claim 1 and claim 27. Applicant submits that said amendments make rejections under 35 U.S.C., first paragraph, moot.

The amendments and arguments found in the response of 5/11/06 have been carefully considered but are not deemed to be persuasive. The amended claims are drawn to methods comprising using any type of tissue sample and methods using almost any probe or primer. For the reasons found in the Final Rejection, of 8/24/05 and 3/13/06, it is suggested that Applicant add the limitations recited in claim 23 to independent claim 1, which recite using tissue samples from the head, neck, or prostate. Further, it is noted that the term "a nucleic acid having a sequence of either SEQ ID NO:1 or SEQ ID NO:3" is inclusive of sequences sharing as few as two consecutive nucleic acids with SEQ ID NO:1 or SEQ ID NO:3 (see claim 1). It is further noted that the term "a nucleic acid having a sequence of either nucleotides 621-1321 of SEQ ID NO:1 or nucleotides 626-1321 of SEQ ID NO:3" is inclusive of sequences sharing as few as two consecutive nucleic acids with sequence of either nucleotides 621-1321 of SEQ ID NO:1 or nucleotides 626-1321 of SEQ ID NO:3. One of skill in the art would recognize that primers or probes specific for the vast majority of these sequences would *not* hybridize to SEQ ID NO:1 or SEQ ID NO:3. It is suggested that Applicant amend the claims to recite: "...a nucleic acid having a-the sequence of either

SEQ ID NO:1 or SEQ ID NO3..." and "...a nucleic acid having a the sequence of either nucleotides 621-1321 of SEQ ID NO:1 or nucleotides 626-1321 of SEQ ID NO:3...".

### ***Summary***

No claim is allowed. Claims 1, 23-25, 27, and 28 are rejected under 35 U.S.C. 112, first paragraph, but free of the prior art teaching a method for detecting the presence of at least one of squamous cell carcinoma and prostate cancer comprising detecting SEQ ID NO:1 or SEQ ID NO:3. The closest prior art for claims 1, 23-25, 27, and 28 are the teachings of Baker et al (US patent application publication US 2003/0073129, with priority to at least 10/98) of a sequence that would bind SEQ ID NO:3; however, this reference does not teach or suggest a method for detecting the presence of at least one of squamous cell carcinoma and prostate cancer.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA



JEFFREY SIEW  
SUPERVISORY PATENT EXAMINER